IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Juturu, et al.
Appl. No.	:	10/509,487
Filed	:	September 27, 2004
For	:	CHROMIUM COMPOSITIONS AND METHODS FOR USING THE SAME FOR INHIBITING DRUG-INDUCED INSULIN RESISTANCE
Examiner	:	Stone, Christopher R.
Group Art Unit	:	1614

ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES
APPELLANT'S BRIEF

Mail Stop Appeal Brief – Patents
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants appeal the rejection of Claims 1-8, 12 and 13 in the above-captioned patent application. These claims were rejected in a final Office Action mailed February 4, 2009. Appellants filed a Notice of Appeal on May 4, 2009. Appellants hereby request a two-month extension of time by payment of the appropriate fee submitted herewith.

I. REAL PARTY IN INTEREST

Pursuant to 37 C.F.R. 41.37(c)(1), Appellants hereby notify the Board of Patent Appeals and Interferences that the real party in interest is the assignee of record for this application, Nutrition 21, Inc., 4 Manhattanville Rd., Suite 202, Purchase, NY 10577-2197.

II. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any other related appeals or interferences, as defined by 37 C.F.R. § 41.37(c)(ii).

III. STATUS OF THE CLAIMS

Claims 1-8, 12 and 13 are pending and stand finally rejected in a final Office Action mailed February 4, 2009, and in the Advisory Action mailed April 16, 2009. Claims 9-11 and 14-50 are withdrawn. Claims 1-8, 12 and 13 are the subject of this appeal. The claims attached hereto as Appendix A reflect the claims on appeal.

IV. STATUS OF AMENDMENTS

The claims have not been amended subsequent to the final Office Action mailed February 4, 2009. The claims on appeal are those entered by the Examiner in the Office Action mailed February 4, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent Claim 1 reads:

> 1. A method for inhibiting the development of drug-induced insulin resistance comprising:
> identifying an individual receiving a dose of a drug that induces insulin resistance; and
> administering to said individual a contemporaneous dose of a dietary chromium complex wherein the amount of chromium complex administered is an amount effective to inhibit the development of insulin resistance.

While not wishing this description to be a substitute for specific claim limitations, in general, the claimed subject matter on appeal relates to methods of inhibiting the development of drug-induced insulin resistance. *See, e.g.*, paragraphs [0016], [0024], [0025], and [0045].

Dependent Claim 2 specifies various drugs that induce insulin resistance. (Specification, at paragraph [0017]). Dependent Claim 3 specifies that the amount of chromium is at least 50μg/day. (Specification, at paragraph [0018]). Dependent Claim 4 specifies that the chromium is a trivalent chromium complex. (*Id.*) Dependent Claim 5 specifies that the chromium complex is selected from chromium picolinate, chromic tripicolinate, chromium nicotinate, chromic polynicotinate, chromium chloride, chromium histidinate, and chromium yeasts. (*Id.*) Dependent Claim 6 specifies that the chromium complex is in a pharmaceutically acceptable carrier. (Specification, at paragraph [0019]). Dependent Claim 7 specifies that the chromium

complex is orally administered. (Specification, at pa ragraph [0036]). Dependent Claim 8 specifies that the chromium complex is parenterally administered. (*Id.*) Dependent Claim 12 specifies that the chromium complex and drug that induces insulin resistance are administered simultaneously. (Specification, at paragraph [0021]). Dependent Claim 13 specifies that the chromium complex is administered within 24 hours of the drug that induces insulin resistance. (*Id.*).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The first ground of rejection to be reviewed on appeal is the Examiner's rejection of Claims 1-7, 12 and 13 under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent Publication No. 2002/0086065 to Katz et al. ("Katz") in view of Godsland et al. ((1992) *J. Endocrin. Metab.* 74(1):64-70) ("Godsland"). The second ground of rejection to be reviewed on appeal is the Examiner's rejection of Claim 8 under 35 U.S.C. § 103(a) as allegedly being obvious over Katz and Godsland, further in view of Goodman and Gillman, ((1995) *The Pharmacological Basis of Therapeutics* 8th Edition) ("Goodman and Gilman").

VII. APPELLANTS' ARGUMENT

a. Background

Appellants appeal the Examiner's rejection of Claims 1-7, 12 and 13 under 35 U.S.C. § 103(a) as allegedly being obvious over Katz in view of Godsland, and the rejection of Claim 8 under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Katz in view of Godsland and Goodman and Gilman.

In an Office Action mailed July 10, 2008, the Examiner rejected Claims 1-7, 12 and 13 under 35 U.S.C. § 102(e), as allegedly being anticipated by Katz. The Examiner stated that Katz teaches a composition for oral administration comprising chromium picolinate and ibuprofen, in a single tablet. The Examiner argued that as such, Katz inherently teaches a method of decreasing insulin resistance, even though "Katz does not explicitly teach that chromium picolinate antagonizes the insulin resistance-increasing activity of ibuprofen." (Office Action mailed July 10, 2008, at 3) (emphasis added). The Examiner also argued that Claim 8 was obvious over Katz in view of Goodman and Gilman. The Examiner relied on the reasoning set forth in the rejection under 35 U.S.C. § 102(e), adding that while Katz does not teach parenteral

administration of chromium, as required by Claim 8, it would have been obvious to administer chromium parenterally in view of Goodman and Gilman, which generally teaches advantages of parenteral administration over oral administration.

On November 7, 2008, Appellants filed an Amendment and Response to Office Action. Appellants amended Claim 1 to include the step of "identifying an individual receiving a dose of a drug that induces insulin resistance," and also to specify that that the chromium was contemporaneously administered. Appellants argued that Katz does not anticipate Claims 1-7, 12 and 13, since Katz fails to teach the identification of an individual receiving a dose of a drug that induces insulin resistance. Katz teaches the administration of chromium for the treatment of Polycystic Ovary Syndrome (PCOS), and none of the individuals in Katz are identified as "individuals receiving a dose of a drug that induces insulin resistance," as required by Appellants' claims. Appellants noted that Katz teaches that non-steroidal anti-inflammatory drugs (NSAIDs) facilitate the absorption of chromium, and that as such, Katz teaches some embodiments wherein an individual identified as having PCOS may be administered a composition that includes ibuprofen in addition to chromium. Even in these embodiments, however, the individuals have not been "identified as receiving a dose of a drug that induces insulin resistance," and Katz fails to meet the limitations of Claims 1-7, 12 and 13. (Amendment and Response to Office Action mailed November 7, 2008, at 9). Appellants argued that Claim 8 was not obvious under 35 U.S.C. § 103(a), since the Examiner's assertions that Katz teaches each and every limitation of Claim 1 is not applicable to the amended claims for the reasons set forth in connection with the rejection under 35 U.S.C. § 102, and since Goodman and Gilman was relied upon solely for the teaching of parenteral administration of chromium.

In the final Office Action mailed February 4, 2009, the Examiner withdrew the rejection of Claims 1-7, 12 and 13 under 35 U.S.C. § 102(e). The Examiner rejected Claims 1-7, 12 and 13 as allegedly being unpatentably obvious over Katz in view of Godsland, and rejected Claim 8, as allegedly being unpatentably obvious over Katz in view of Godsland, further in view of Goodman and Gilman. The Examiner stated that Appellants' amendment to the claims necessitated the new grounds of rejection, and made the Office Action final.

Regarding the rejection of Claims 1-7, 12 and 13, the Examiner argued that Katz teaches a method of decreasing insulin resistance comprising the oral administration of chromium picolinate at a daily dose of 1000μg of chromium in a pharmaceutically acceptable carrier. The

Examiner conceded that Katz fails to teach the step of identifying an individual receiving a dose of a drug that induces insulin resistance, as recited in Claim 1, or administering chromium picolinate simultaneously with the drug that induces insulin resistance. (Final Office Action mailed February 4 , 2009 at 3) (emphasis added). The Examiner argued that nevertheless, Godsland teaches that oral contraceptive drugs cause insulin resistance, and thus it would have been *prima facie* obvious to identify an individual receiving a dose of a drug that induces insulin resistance (*i.e.*, oral contraceptives), and to administer chromium picolinate to the subject contemporaneously to alleviate or reduce a known side effect of the drug. (*Id* at 3-4)(Emphasis added). The Examiner stated that the skilled artisan would have a reasonable expectation of success, since it would have been expected that chromium would treat/alleviate the oral contraceptive induced insulin resistance. (*Id.* at 4). Regarding Claim 8, the Examiner stated that even though neither Katz nor Godsland suggest parenteral administration of chromium, parenteral administration of compositions is common, as demonstrated by Goodman and Gilman. (*Id.*)

In response to the final Office Action, Appellants argued that the references do not establish that Claims 1-7, 12 and 13 are *prima facie* obvious, since nothing in Katz or Godsland, alone or in combination, provides the skilled artisan with a reasonable expectation that chromium can *inhibit the development* of insulin resistance. Appellants pointed out that neither reference indicates that chromium complexes can be used in a prophylactic manner to inhibit the development of insulin resistance in individuals that do not already have insulin resistance. Katz relates to the treatment of polycystic ovary syndrome (PCOS), and symptoms associated with PCOS such as obesity, insulin resistance, abnormal lipid profile, excessive hair growth and infertility, with chromium. Although, as suggested by the Examiner, Katz teaches that chromium can "alleviate or reduce" conditions that already exist (Final Office Action, at 3), Katz does not indicate that chromium is useful or would have any benefit in individuals without a preexisting condition, such as PCOS, or even insulin resistance. Godsland is completely silent about chromium and the inhibition of the development of insulin resistance, except for providing the suggestion that alternative estrogens should be considered as an alternative means to reduce the metabolic side effects of oral contraceptives. Accordingly, Appellants argued that the skilled artisan would not have a reasonable expectation of success in practicing Appellants' claimed method based on the teachings of Katz and Godsland, since the combined teachings of the

references provide no reason to expect that chromium can be used to inhibit the development of insulin resistance, *e.g.*, in a subject identified as receiving a dose of oral contraceptives.

In an Advisory Action mailed on April 16, 2009, the Examiner maintained the rejection of Claims 1-8, 12 and 13 under 35 U.S.C. § 103(a). The Examiner stated that Appellants' arguments were unpersuasive because the references render the active steps of identifying an individual receiving a drug that induces insulin resistance and contemporaneously administering a dose of chromium to the individual obvious in view of Katz and Godsland for the reasons already of record.

Thus the issue to be determined is whether the skilled artisan would have a reasonable expectation of inhibiting the development of drug-induced insulin resistance in a subject receiving a dose of a drug, *e.g.*, oral contraceptives, given the teachings of Katz and Godsland, which relate to individuals with preexisting conditions, and whether it would have been obvious to identify a patient population that "is receiving a dose of a drug that induces insulin resistance," that doesn't already have a pre-existing condition.

Appellants submit that the rejections under 35 U.S.C. § 103(a) should be reversed, since there is no reasonable expectation that the administration of chromium would have any effect on the inhibition of the development of drug-induced insulin resistance, *e.g.*, in individuals receiving a dose of oral contraceptives. Because Appellants' claims relate to the inhibition of the development of insulin resistance, the individuals recited in the claims do not have pre-existing insulin resistance.

b. Legal Standard

In order to establish that a claim is *prima facie* the Examiner must articulate specific reasons why any differences between the prior art references would have been obvious to one skilled in the art. M.P.E.P. §2141. Further, there must be a reasonable expectation of success. M.P.E.P. §2143. As discussed below, the differences between Appellants' invention and Katz and Godsland are significant and the references are not sufficient to support a *prima facie* case of obviousness.

c. Claims 1-7, 12 and 13 are Not Obvious over Katz and Godsland

i. Katz and Godsland Do Not Provide a Reasonable Expectation that Chromium is Useful for Inhibiting the Development of Drug Induced Insulin Resistance

Claims 1-7, 12 and 13 are directed to methods of *inhibiting the development* of drug-induced *insulin resistance* while taking a drug that induces insulin resistance by administering an amount of chromium complex sufficient to *inhibit the development* of insulin resistance. Appellants' claims are thus limited to the inhibition of the development of insulin resistance and diseases secondary thereto, in the first place. As such, Applicants' claimed invention reduces subjects' exposure to insulin resistance-associated diseases and risks, or having to undergo additional costly therapy for the treatment of insulin resistance (or related secondary diseases). (Specification, at paragraph [0028]).

The concept of inhibiting the onset of drug-induced insulin resistance is absent and cannot be readily determined from the teachings of the two references relied upon by the Examiner, which both relate to individuals with preexisting conditions. Katz relates to the treatment of polycystic ovary syndrome (PCOS) and symptoms associated therewith. (*See,* Katz, at paragraph [0050], stating: [t]he primary basis of the present invention is the novel and unexpected discovery that chromium complexes lower blood glucose levels, thereby ameliorating some of the symptoms associated with PCOS.") (emphasis added). The methods disclosed in Katz et al. involve the identification of a patient suffering from PCOS, and administration of an "effective dose" of at least one chromium complex. (*Id.*). According to Katz, an effective dose is a dose that "treats or reduces" at least one symptom of PCOS. (*Id.*). Katz does not teach that chromium supplementation is useful to inhibit the development of insulin resistance while taking a drug that induces insulin resistance in individuals that do not already have PCOS, or its associated conditions, such as insulin resistance. In fact, nothing in Katz et al. would lead the skilled artisan to expect that chromium complexes can be used to prevent the development of any condition, including insulin resistance.

Godsland suffers from the same deficiencies as Katz, and thus does not support a *prima facie* case under 35 U.S.C. § 103(a), either alone or in combination with Katz. The Examiner relied upon the teachings of Godsland solely for the proposition that oral contraceptives cause insulin resistance. Godsland suggests that oral contraceptive-induced metabolic changes are due

to the combined effects of estrogen and progestin on insulin half-life, insulin secretion, and insulin resistance. (*See,* Godsland, at Abstract). As noted above, the individuals in Godsland had been taking oral contraceptives for at least three consecutive months. (Godsland, at 64, Col. 2). The oral contraceptives in the study included combined formulations of ethinyl estradiol with levonorgestrel, desogesterel or norethindrone, and a formulation containing norethindrone alone. Godsland analyzed the effect of the various oral contraceptives on insulin resistance, insulin secretion and insulin metabolism. Godsland reported that the norethindrone alone "did not affect insulin sensitivity." (Godsland, at 68, Col. 1). The levonorgestrel combination increased the pancreatic insulin secretion rate. (*Id.*, at 69, Col. 2). The desogestrel combination increased insulin half-life. (*Id.*). Although Godsland did not test the effects of the norethindrone combination on insulin half-life or insulin secretion, the authors noted that "[a]n increase in insulin half-life, similar to that seen with the desogestrel combination in the present study, has been demonstrated in users of norethindrone-type combinations containing. . .ethinyl estradiol." (*Id.*). Godsland concluded that whereas estrogen was primarily responsible for insulin resistance, the metabolic changes observed in individuals taking oral contraceptives was due to the combined effects of estrogen and progestin. (*Id.*, at Abstract). The teachings of Godsland indicate that metabolic changes in individuals taking oral contraceptives are likely the result of differing effects of the components of oral contraceptives on insulin secretion, insulin half-life, and insulin sensitivity. Godsland is completely silent regarding the inhibition of the development of insulin resistance, except for providing the suggestion that the use of alternative estrogens should be considered as a potential means to reduce the metabolic side effects of oral contraceptives. (Godsland, p. 69, Col 2). Godsland is also completely silent regarding chromium, or any potential uses of chromium. There is nothing in Godsland that would provide the skilled artisan with a reasonable expectation that the administration of chromium would provide beneficial effects in preventing the occurrence of any of the physiological effects of oral contraceptives. Thus, nothing in Godsland would lead the skilled artisan to administer chromium complexes to an individual, for any reason, including the inhibition of the development of insulin resistance, *e.g.*, in individuals receiving a dose of an oral contraceptive. Accordingly, Godsland et al. do not cure the deficiencies in the teachings of Katz discussed above.

Appellants submit that the Examiner has failed to articulate reasoning that would indicate why a composition that has been identified as being useful for the treatment of a complex disease

in which individuals present with numerous symptoms including several metabolic disturbances, would be useful for inhibiting the development of one metabolic disturbance, *i.e.*, drug-induced insulin resistance. Appellants respectfully submit that under the Examiner's logic, it would be obvious and useful to administer a chemotherapeutic agent to a subject receiving an X-ray to inhibit the development of cancer, since exposure of X-radiation is known to cause cancer. The Examiner's reasoning is untenable, in the absence of a clear articulation of why one skilled in the art would expect that administration of chromium would be useful in inhibiting the development of insulin resistance. Without evidence or reasoning of why chromium would be expected to inhibit the development of insulin resistance, Appellants' claimed methods are not obvious in view of Katz, which teaches administration of chromium for the treatment of PCOS, or one or more of the symptoms of PCOS, either alone, or in combination with Godsland.

As neither Katz nor Godsland, alone or in combination, provides any teaching that would lead the skilled artisan to reasonably believe that chromium supplementation is useful to prevent the signs of insulin resistance from developing, the skilled artisan would have no reasonable expectation of success and the references thus fail to support a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

ii. The Identification of the Recited Patient Population is Not Obvious in View of Katz and Godsland

Appellants' claimed method relates to the inhibition of the development of drug-induced insulin resistance. Thus, the individuals recited in the claims do not have pre-existing insulin resistance. Because Katz and Godsland are silent regarding the inhibition of the onset of drug-induced insulin resistance, Appellants' claimed method, which relates to a population of individuals in which the development of insulin resistance can be inhibited, *i.e.*, individuals are not already insulin resistant, and that are receiving a dose of a drug that induces insulin resistance, is not obvious in view of the teachings of Katz and Godsland.

As discussed above, Katz relates to "compositions comprising chromium complexes and uses of these chromium complexes in treating Polycystic Ovary Syndrome (PCOS)." (Katz, at paragraph [0003]). According to Katz, "[t]he method includes identifying a subject suffering from PCOS" and administering chromium to the subject. (*Id.*, at paragraph [0045]). Katz teaches that "chromium picolinates. . .are insulin sensitizers." (*Id.*). According to Katz,

chromium functions as a cofactor for insulin, which "binds to the insulin receptor and potentiates many, and perhaps all, of its functions." (*Id.*, at [0038]). Thus, at most, Katz suggests that chromium can be used to treat insulin resistance in individuals that already have insulin resistance. According to Katz, chromium treats insulin resistance by binding to the insulin receptor, and thereby activating the receptor. The teachings of Katz would not lead the skilled artisan to identify a population of individuals receiving a dose of a drug that induces insulin resistance, in whom the development of drug-induced insulin resistance can be inhibited, *i.e.*, that do not already have insulin resistance. Further, the Examiner has not articulated a specific reason why it would have been obvious to identify this population of individuals.

The identification of and administration of chromium to individuals receiving oral contraceptives, and in whom the development of insulin-resistance can be inhibited, would not have been obvious in view of Godsland, either alone or in combination with Katz. As discussed above, Godsland relates to individuals that have been taking oral contraceptives for several months, and provides a discussion of the levels of insulin resistance, insulin metabolism, and insulin secretion in these individuals. Nothing in Godsland would render the identification of a subset of individuals receiving oral contraceptives, and in whom the development of insulin resistance could be inhibited, obvious.

Neither Katz nor Godsland, alone or in combination, would provide the skilled artisan with a reason to identify a population of individuals receiving a dose a drug that causes insulin resistance, and to administer chromium to inhibit the development of insulin resistance. Thus, the references do not render Claims 1-7, 12 and 13 obvious under 35 U.S.C. § 103(a).

d. Claim 8 is not Obvious in view of Katz, Godsland, and Goodman and Gilman

For the reasons set forth above, Katz and Godsland do not render Appellants' claimed method of inhibiting the development of drug-induced insulin resistance, including identifying an individual receiving a dose of a drug that induces insulin resistance, and administering a contemporaneous dose of a dietary chromium complex to the individual, wherein the amount of chromium complex administered is an amount effective to inhibit the development of insulin resistance, obvious under 35 U.S.C. § 103(a).

Goodman and Gilman is completely silent about the inhibition of the development, or even the treatment of pre-existing insulin resistance. Goodman and Gilman is completely silent about chromium. Accordingly, the teachings of Goodman and Gilman are irrelevant to the patentability of independent Claim 1, from which Claim 8 depends. Appellants submit that Claim 8 is not obvious under 35 U.S.C. § 103(a) in view of Katz, Godsland and Goodman and Gilman, for the reasons discussed in connection with Claims 1-7, 12 and 13, above.

e. ***Obviousness - Conclusion***

Appellants have demonstrated, and the Examiner has agreed, that the cited art does not teach the inhibition of the development of drug-induced insulin resistance, or the identification of individuals receiving a dose of a drug that induces insulin resistance, for the administration of chromium to inhibit the development of insulin resistance. The Examiner's rejections under 35 U.S.C. § 103(a) are based on the Examiner's assertion that, in view of Katz, "chromium picolinate was known to treat insulin resistance and would have been expected to treat/alleviate the oral contraceptive induced insulin resistance," (Final Office Action mailed February 4, 2009, at 3-4) (emphasis added), and that it would have been obvious to identify individuals receiving oral contraceptives "and then to administer chromium picolinate with said drug to alleviate/reduce a known side effect of the drug." (*Id.* at 3).

The Examiner has failed to establish that the skilled artisan would have any reasonable expectation of successfully inhibiting the development of drug-induced insulin-resistance, however. Because the skilled artisan would not have reason to believe that chromium provides prophylactic benefits, and can function to inhibit the development of a condition, *i.e.*, drug-induced insulin resistance, it would not have been obvious to identify individuals in whom the development of insulin resistance could be inhibited, and who re receiving a dose of a drug that induces insulin resistance, and to administer chromium to those individuals. Accordingly, Appellants respectfully request that the Board reverse the Examiner's rejection of Claims 1-8, 12 and 13 under 35 U.S.C. § 103(a) as being obvious over Katz, in view of Godsland.

2. ***Conclusion***

In view of the arguments presented above, Appellants submit that Claims 1-8, 12 and 13 are not obvious over the cited references. Appellants therefore request that the Board reverse the Examiners rejections under 35 U.S.C. § 103(a).

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 3, 2009

By: Kathleen R. Mekjian

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VIII. APPENDIX A – CLAIMS ON APPEAL

1. (Previously presented) A method for inhibiting the development of drug-induced insulin resistance comprising:

identifying an individual receiving a dose of a drug that induces insulin resistance; and

administering to said individual a contemporaneous dose of a dietary chromium complex wherein the amount of chromium complex administered is an amount effective to inhibit the development of insulin resistance.

2. (Original) The method of Claim 1, wherein said drug is selected from the group consisting of statins, non-steroidal anti-inflammatory drugs, steroids, oral contraceptives, hormone replacement therapy, beta blockers, potassium channel openers, immuno-suppressants, and diuretics.

3. (Original) The method of Claim 1, wherein the effective dose of chromium provided by said chromium complex is at least about 50 μg per day.

4. (Original) The method of Claim 1, wherein said chromium complex is a trivalent chromium complex.

5. (Original) The method of Claim 1, wherein said chromium complex is selected from the group consisting of chromium picolinate, chromic tripicolinate, chromium nicotinate, chromic polynicotinate, chromium chloride, chromium histidinate, and chromium yeasts.

6. (Original) The method of Claim 1, wherein said chromium complex is in a pharmaceutically acceptable carrier.

7. (Original) The method of Claim 1, wherein said chromium complex is orally administered.

8. (Original) The method of Claim 1, wherein said chromium complex is parenterally administered.

9-11. (Withdrawn)

12. (Original) The method of Claim 1, wherein said chromium complex and said drug that induces insulin resistance are administered simultaneously.

13. (Original) The method of Claim 1, wherein said chromium complex is administered within 24 hours of said drug that induces insulin resistance.

14-50. (Withdrawn)

IX. APPENDIX B – EVIDENCE

Attached hereto is a copy of the evidence cited in Appellants' Brief. The list of evidence below is accompanied by a statement setting forth where in the record that evidence was entered into the record by the Examiner.

Tab	Reference	Submitted	Entered
1	U.S. Patent Application Publication No. 202/0086065 to Katz et al.		Cited by the Examiner in the Office Action mailed July 10, 2008.
2	Goodman and Gilman, "the Pharmacological Basis of Therapeutics," Pergamon Press, 8th Ed., pp. 5-6, 1992.		Cited by the Examiner in the Office Action mailed July 10, 2008.
3	Godsalnd, et al. (1992), *J. Clin. Endocrin. Metab.* 74(1):64-70.		Cited by the Examiner in the final Office Action mailed February 4, 2009.

X. APPENDIX C – RELATED PROCEEDINGS

There are no decisions rendered by a court or the Board in any related proceedings identified above, as defined by 37 C.F.R. § 41.37(c)(ii).

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